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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------|------------------|
| 10/621,623  | 07/16/2003  | Ben-Zion Dolitzky    | 1662/60707            | 2588             |
| 26646   | 7590        | 10/16/2006           | EXAMINER              |                  |
| KENYON & KENYON LLP<br>ONE BROADWAY<br>NEW YORK, NY 10004 |             |                      | STOCKTON, LAURA LYNNE |                  |
|   |             |                      | ART UNIT              | PAPER NUMBER     |
|   |             |                      | 1626                  |                  |

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                          |                     |  |
|------------------------------|--------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>   | <b>Applicant(s)</b> |  |
|                              | 10/621,623               | DOLITZKY ET AL.     |  |
|                              | <b>Examiner</b>          | <b>Art Unit</b>     |  |
|                              | Laura L. Stockton, Ph.D. | 1626                |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-16 and 18 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

**Claims 1-18 are pending in the application.**

### ***Election/Restrictions***

Applicants' election without traverse of Group II (claims 11-18) in the reply filed on October 28, 2005 was acknowledged in the previous Office Action. The requirement was deemed proper and therefore made FINAL in the previous Office Action.

Claims 1-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in the reply filed on October 28, 2005.

Rejections made in the previous Office Action that do not appear below have been overcome by Applicants'

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amendment to the claims. Therefore, arguments pertaining to these rejections will not be addressed.

### ***Response to Arguments***

Applicant's arguments with respect to claims 11-16 and 18 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

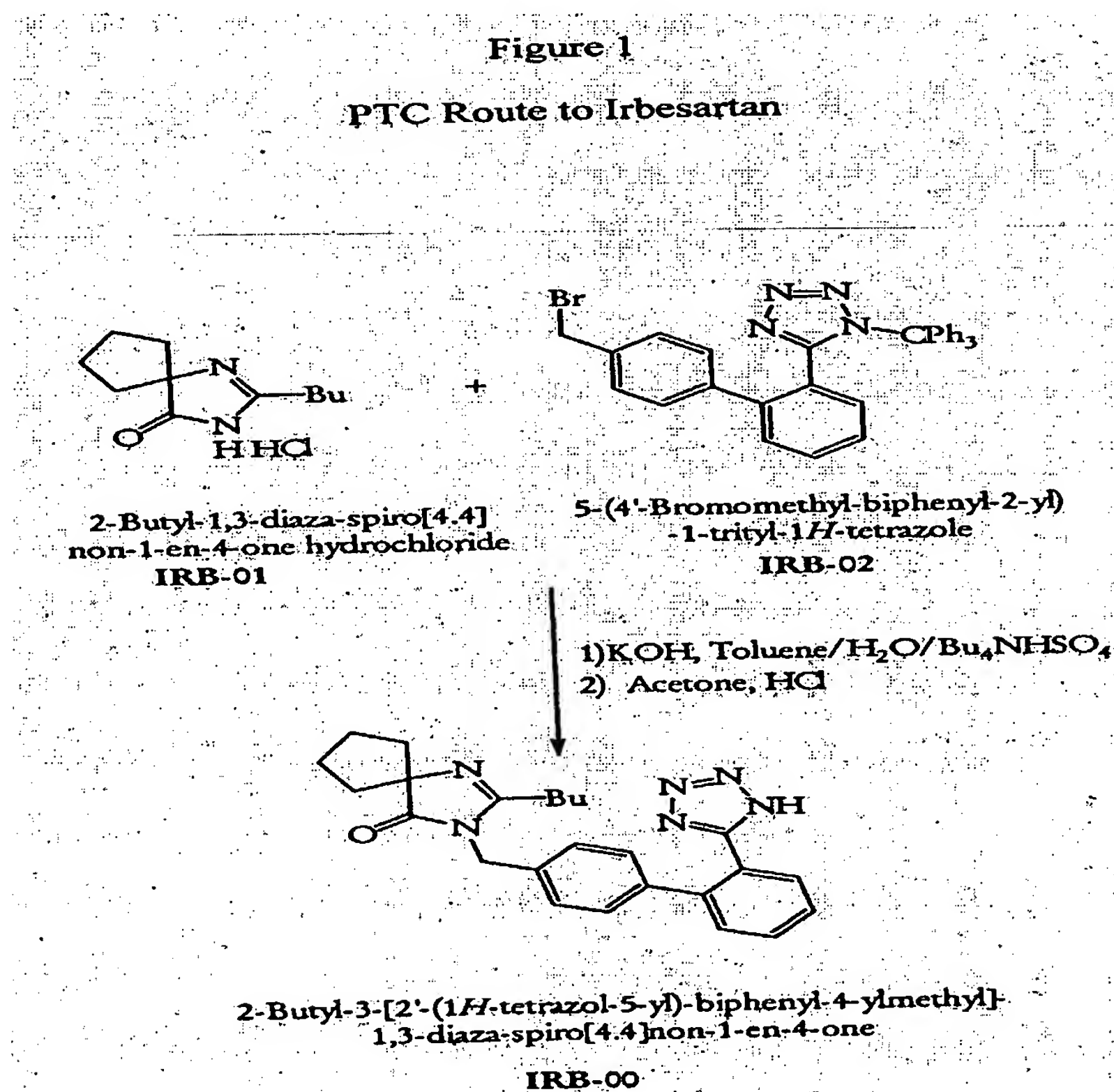
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 11-16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernhart et al. {U.S. Pat. 5,270,317} in combination with Anderson et al. {WO 99/38847}.

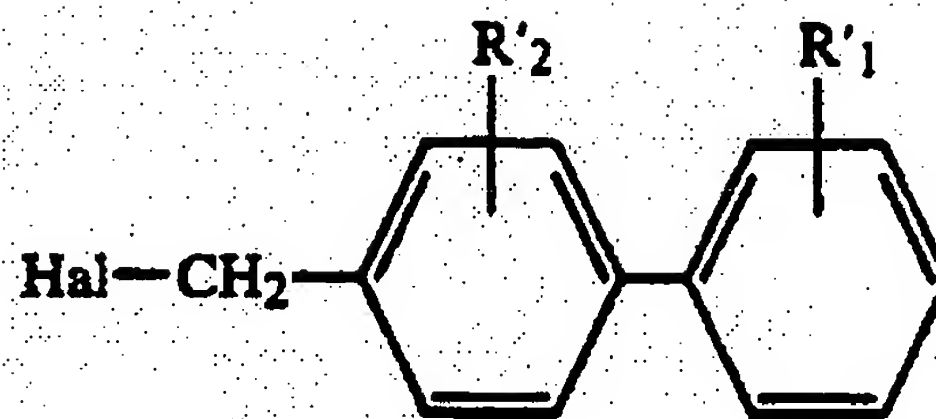
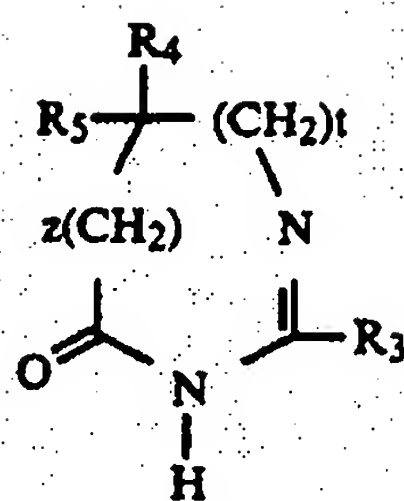
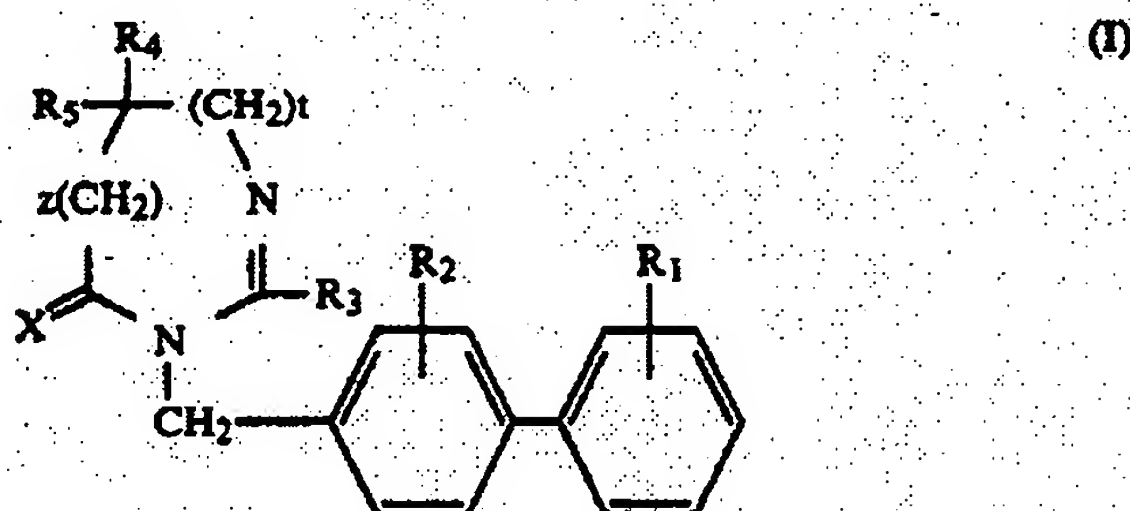
*Determination of the scope and content of the prior art (MPEP §2141.01)*

Applicants claim a process of making irbesartan by the process found in instant Figure 1 (reproduced below).



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Bernhart et al. (columns 1-4) teach a process of making N-substituted heterocyclic compounds of formula (I) (reproduced below) wherein a compound of formula 2 (reproduced below) is reacted with a compound of formula 3 (reproduced below).



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Note in Bernhart et al. that variable  $R_2$  can be hydrogen and  $R_1$  can represent tetrazolyl and cyano (column 1, lines 52-56). Also see the process in column 9, lines 54-62, the products and the processes of making Example 5A) and Example 5C) in columns 20 and 21. Bernhart et al. further teach that it is well within the skill of one skilled in the art to convert, for example, tetrazolyl protected by a trityl group or a cyano group to a tetrazolyl group by known methods (column 9, lines 15-28).

~~*Ascertainment of the difference between the prior art and the claims*~~

*(MPEP §2141.02)*

Bernhart et al. do not teach the use of a phase transfer catalyst in the process.

*Finding of prima facie obviousness--rational and motivation (MPEP*

*§2142-2413)*

However, Anderson et al., which reference Bernhart et al. on page 2, teach the use of a phase transfer catalyst in the process taught by Bernhart et al. (page

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4). Anderson et al. further teach the temperature, pressure, solvents, etc. (pages 7-10).

One skilled in the art would thus be motivated to combine the teachings of Bernhart et al. and Anderson et al. to arrive at the instant claimed process with the expectation of obtaining Irbesartan in short duration and with increased productivity as taught by Anderson et al. (page 7, lines 27 through to page 8, lines 1-2). The instant claimed process would have been suggested to one skilled in the art and therefore, would be obvious to one skilled in the art.

#### ***Allowable Subject Matter***

Claim 17 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

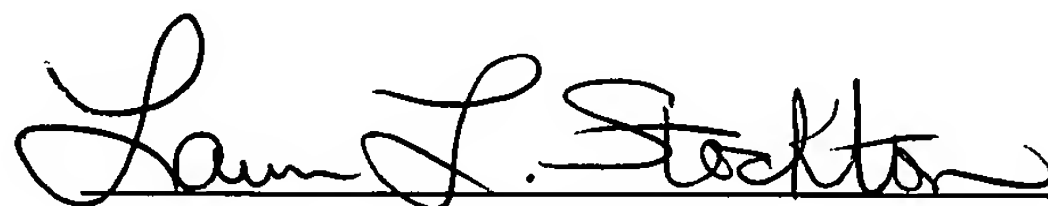


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



Laura L. Stockton, Ph.D.  
Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600

October 5, 2006